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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,631	07/28/2003	Marc Achen	28967/5680D	3314

4743 7590 10/31/2007
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EXAMINER

HUYNH, PHUONG N

ART UNIT	PAPER NUMBER
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1644

MAIL DATE	DELIVERY MODE
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10/31/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/627,631	ACHEN ET AL.	
	Examiner	Art Unit	
	Phuong Huynh	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 04 September 2007.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 9-13, 41 and 45-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 9-13, 41 and 45-47 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application
- 6) Other: _____.

DETAILED ACTION

1. Claims 9-13, 41 and 45-47 are pending.
2. The following new grounds of rejections are necessitated by the amendment filed 9/4/07.
3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.
4. Claims 9-13, 41 and 45-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 45 is indefinite because the metes and bounds of what would constitute the "size" of unprocessed VEGF-D in the sample cannot be determined.

Further, Claim 45 is incomplete for missing step for contacting the sample with an antibody that binds to the unprocessed full-length VEGF-D polypeptide. The remaining claims are rejected for depending from said rejected claim 45.
5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless –
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
6. Claims 9-13, 41 and 45-47 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 99/33485 publication (of record, published July 8, 1999, PTO 1449).

The WO 99/33485 publication teaches a method for diagnosing neoplastic disease such as human malignant melanoma as an indicator of future metastatic risk. The reference method steps comprise: obtaining a sample such as a biopsy tissue specimen from human patient with melanoma (See page 20, lines 1-10, page 32 at line 18, in particular), exposing the biopsy specimen to a composition comprising an antibody such as monoclonal antibody 4A5 (later renamed as VD1 as evidenced in page 48 of instant specification that bind specifically to unprocessed (full-length) VEGF-D) for immunohistochemistry analysis (See page 32, lines 18-

Art Unit: 1644

19, in particular), measuring the presence or increase (amount) in the VEGF-D expression in or around a potential neoplastic growth (See pages page 20, lines 1-10, pages 33-35, Figs 7A-E, claims 28-30, in particular). The reference teaches VEGF-D monoclonal antibodies detected VEGF-D in melanoma cells in both clinical samples, and the detection of VEGF-D indicates these tumor cells are most likely producing said VEGF-D (See page 35, lines 13-15, in particular). The recitation of measuring the size of the VEGF-D polypeptide is inherently to the reference antibody since the reference antibody 4A5 binds to the unprocessed VEGF-D or full-length (VEGF-D) in the sample. Further, as evidenced at pages 48-49 of instant application, the antibody used by applicant to detect the "size" of VEGF-D in formalin fixed and paraffin embedded tissue section (immunohistochemistry) is the same antibody used for immunohistochemistry as that of the WO 99/33485 publication. The reference antibody includes a detectable label such as Streptavidin-alkaline phosphatase, enzyme labels such as horseradish peroxidase, or fluorimetric labels such as fluorescein-5-isothiocyanate (FITC) (see pages 20, 33, claim 30 of the WO 99/33485, in particular). The increase amount of VEGF-D is evidenced by the more pronounced staining in small islands of tumor cells at the periphery of the invasive portion of the tumor, which correlates with increased tumor growth or metastatic risk (see page 34, lines 8-15, Figure 7A-B, in particular). Claim 47 is included in this rejection because the reference teaches VEGF-D is stained positively in the cytoplasm of the endothelial cells in the tumor section (see page 34, line 18-20, Figure 7C, page 35, line 15-21, in particular). Claim 41 is included in this rejection because the WO 99/33485 publication teaches breast cancer associated with lymph node metastasis and obstruction; increasing amount of the VEGF-D induces lymphangiogenesis (see page 17, line 11-17, in particular).

7. No claim is allowed.
8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

Art Unit: 1644

will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh, Ph.D. whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Thursday from 9:00 a.m. to 6:30 p.m. and alternate Friday from 9:00 a.m. to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The IFW official Fax number is (571) 273-8300.
10. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phuong N. Huynh, Ph.D.

Patent Examiner

Technology Center 1600

October 26, 2007

Christina Chan
CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600